

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE)	MDL NO. 1456
LITIGATION)	
)	CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO)	
ALL CLASS ACTIONS)	Judge Patti B. Saris
)	

**TAP PHARMACEUTICAL PRODUCTS INC.'S SEPARATE
REPLY IN SUPPORT OF ITS MOTION TO DISMISS
PLAINTIFFS' AMENDED MASTER CONSOLIDATED COMPLAINT**

I. Plaintiffs Do Not Explain How TAP Can Compete On The “Spread” For Prevacid®

Plaintiffs accuse TAP of manipulating the AWP of Prevacid® to increase its market share. Plaintiffs do not, however, explain how TAP could gain competitive advantage by manipulating the AWP for Prevacid®. As explained in TAP’s memorandum in support of its motion to dismiss, this failure to describe a scheme that makes economic sense is fatal to plaintiffs’ claims. *See, e.g., Interface Group, Inc. v. Massachusetts Port Auth.*, 816 F.2d 9, 12 (1st Cir. 1987).

As to all drugs named in the AMCC, plaintiffs contend that individual manufacturers inflated AWP to increase market share. *See* AMCC ¶ 6. Plaintiffs first asserted this theory in the MCC, basing it on the methodology by which Medicare calculates payments for physician-administered drugs. Under that methodology, Medicare pays providers for single-source drugs based upon the AWP of each, individual product. *See* 42 C.F.R. § 405.517(b). Thus, plaintiffs allege, a provider has an incentive to choose the drug with the greatest “spread” between AWP and acquisition cost. *See* AMCC ¶ 6.

Plaintiffs’ alleged theory about AWP manipulation cannot apply in all contexts. This Court, for example, already has found that the theory does not apply to multiple-source drugs covered by Medicare Part B, where individual drugs are not paid based upon separate AWPs, but instead are paid at a flat rate based on a median AWP. *See* 42 C.F.R. § 405.517(c); *AWP Litigation*, 263 F. Supp. 2d at 194. In determining whether plaintiffs’ theory might apply outside the context of single-source drugs covered by Medicare Part B, this Court should look for three necessary elements:

1. A competitive, therapeutic equivalent must exist.
2. The provider who chooses the drug must receive payment directly.
3. The payment for the two competing drugs must be based upon each drug’s individual AWP. *See, e.g.,* 42 C.F.R. § 405.517(b).

If any one of these factors is not present, plaintiffs' theory makes no economic sense in the context of that drug and that payment methodology.

In the AMCC, plaintiffs expand their case beyond Medicare to capture private payors. Consequently, this Court must address whether plaintiffs' theory of AWP manipulation applies in the private payor arena. In doing so, the Court cannot look to Medicare regulations to determine how private entities calculate payments. Instead, the Court must rely on the allegations of the AMCC. Accordingly, the AMCC must allege facts sufficient to satisfy the elements described above as to each drug for which a claim is made in the private payor context.

Prevacid[®] is an example of a brand name drug for which plaintiffs have not made sufficient allegations to assert a claim of AWP manipulation. Prevacid[®] is an oral prescription medication not covered by Medicare Part B. Thus, the only claims plaintiffs pursue for Prevacid[®] relate to private payors. Those claims must be dismissed because the AMCC's allegations do not satisfy the factors enumerated above.

1. The AMCC does not identify a competitive, therapeutic equivalent for Prevacid[®].

Although plaintiffs purport to describe a competitor for Prevacid[®] in their opposition (Pl. Sep. Mem. at 20), that allegation does not appear in the AMCC. *See Wright v. Ernst & Young*, 152 F.3d 169 (2nd Cir. 1998) (complaint cannot be amended by pleadings on motion to dismiss).

2. The providers who write prescriptions for Prevacid[®] do not receive payment directly.

The AMCC does not allege that the providers who prescribe Prevacid[®] receive payment for prescribing or administering the drug. In fact, they do not. A physician who sends her patient to the pharmacy to buy Prevacid[®] receives no AWP-based (or other) payment. The AMCC nowhere explains how a physician has a financial incentive to prescribe Prevacid[®] in place of any other drug. Despite a lengthy discussion of PBM operations (AMCC parag. 171), the

AMCC likewise does not explain how a PBM affects a physician's prescribing decision regarding Prevacid®.

3. *Payment for Prevacid® is not alleged to be based on its individual AWP.* The AMCC contains no allegations regarding the method by which any private entity calculates the payment amount for Prevacid®. This is true even for plaintiffs UFCW, TCBW, THWF, CMHV, MAN-U and PFTHW, all of whom allegedly paid for Prevacid®. Specifically, none of these private payor plaintiffs alleges that it paid for Prevacid® based on the drug's individual AWP.

II. Plaintiffs Allege No Fraudulent Conduct For Prevacid®

In the AMCC, plaintiffs describe no specific conduct by TAP relating to the pricing or marketing of Prevacid®. Instead, plaintiffs describe alleged conduct relating to Lupron®. *See, e.g.,* AMCC ¶¶ 508, 511, 518. In their opposition, plaintiffs continue this misguided strategy, spilling page upon page of ink about Lupron® without even mentioning Prevacid®. *See* Pl. Sep. Mem. at 73-75. One can only surmise that plaintiffs have nothing to allege regarding Prevacid®. Because Lupron® is not at issue in this case, all counts relating to TAP should be dismissed.

III. TAP Is Not A Member Of Together Rx

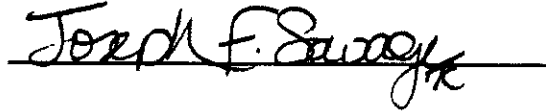
TAP's alleged membership in Together Rx is the only basis on which plaintiffs name TAP in Counts V through VIII and X of the AMCC. *See* AMCC ¶ 543. This allegation is flatly contradicted by the Together Rx website. *See* TAP Mem., Exs. A & B. Because plaintiffs cite the website in their complaint (AMCC ¶¶ 562, 578-82), this Court is entitled to rely on it in deciding this motion to dismiss. *See Beddall v. State St. Bank & Trust Co.*, 137 F.3d 12, 17 (1st Cir. 1998). Accordingly, this Court should reject plaintiffs' incorrect suggestion that TAP is a member of Together Rx and dismiss Counts V through VII and X as to TAP.

IV. Conclusion

This Court should dismiss the Amended Master Consolidated Complaint as to TAP.

Respectfully Submitted,

Dated: September 30, 2003

A handwritten signature in black ink, reading "Joseph F. Savage", is written over a horizontal line.

Joseph F. Savage (BBO# 443030)
TESTA HURWITZ & THIBEAULT LLP
125 High Street
Boston, Massachusetts 02110-2704
Telephone: (617) 248-7000
Facsimile: (617) 790-0297

Daniel E. Reidy
JONES DAY
77 West Wacker Drive
Chicago, Illinois 60601
Telephone: (312) 782-3939
Facsimile: (312) 782-8585

***Counsel for Defendant TAP Pharmaceutical
Products Inc.***